UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,298	08/18/2003	Ann de Wees Allen	ALL-T101D1	4203

23557 7590 06/20/2007

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,298	ALLEN, ANN DE WEES	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-9 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-9,12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 6-9 and 12-15 are presented for examination.

Applicant's Amendment filed April 4, 2007 has been received and entered into the present application.

Claims 1-3, 6-9 and 12-15 are pending and under examination. Claims 5 and 11 are cancelled and claims 1, 3, 6, 9, 12 and 14 are amended.

Applicant's arguments and amendments to the claims, filed April 4, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-9 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 1, for example, and also present claims 6 and 11, define compositions "wherein said composition further comprises an amino acid component that consists of a muscle growth stimulating amount of L-arginine, L-leucine, L-isoleucine, and L-valine; and wherein said composition does not contain any amino acids except the amino acids in the amino acid component."

In particular, it is noted that the composition defined in present claims 1, 6 and 11 does not clearly delineate what components are intended to be included and what components are to be excluded from the composition because of the conflicting transitional language that is present in the claims.

Applicant attempts to limit the amino acid component only to L-arginine, L-leucine, L-isoleucine and L-valine by using the transitional phrase "consists of" to define the "amino acid component", but leaves the overall composition open to the recited elements (i.e., chromium, choline, sodium borate and/or vitamin B5) and also to the inclusion of additional, unrecited elements. In other words, the claims do not definitively preclude the inclusion of additional components. This may reasonably include, for example, fructose, trans-ferulic acid or even other amino acids.

Though Applicant's proviso that the composition not contain any other amino acids except the amino acids in the amino acid component, the fact remains that the conflicting nature of the transitional language present in the claims fails to clearly set forth whether the composition, in fact, is solely limited to the recited four amino acids (i.e., L-arginine, L-leucine, L-isoleucine and L-valine) or the composition is still open to the inclusion of additional elements, which could reasonably be interpreted to read upon the inclusion of additional amino acids. Applicant has failed to clearly, precisely and deliberately set forth the transitional language that he intends to control the overall constitution of the claimed composition. As a result, the claims read equally upon two interpretations: (1) wherein the composition is closed to the inclusion of additional amino acid components and (2) wherein the composition remains open to the inclusion of additional amino acid components.

Again, though it may be Applicant's intent to exclude additional amino acids other than L-arginine, L-leucine, L-isoleucine and L-valine, it is unclear how Applicant would attempt to actually achieve such an objective if the composition is a homogenous mixture and clearly allows for the presence of other components due to the fact that Applicant describes the overall composition with open language. Thus, for example, one of skill in the art at the time of the invention could conceivably include additional amino acids other than the arginine, leucine, isoleucine and valine of the "amino acid component" as supplementary amino acids that are not considered part of the "amino acid component" *per se*. The

claims, therefore, as written do not clearly convey the composition that it appears Applicant wishes to claim.

In addition, it is noted that present claims 3 and 9 do not narrow the subject matter of the independent claim from which they depend. In fact, it appears that present claims 3 and 9 actually broaden the composition of the independent claim because each of the claims recites "wherein said composition comprises per dosage" and then goes on to describe the dosage ranges of each of the components. Regarding the amino acids, Applicant expressly recites the L-arginine, L-leucine, L-isoleucine and L-valine amino acid components, but it is noted that the use of the word "comprises" in this claim leaves the claim open to the inclusion of any one or more additional ingredients, which may again, reasonably, include additional amino acids.

Therefore, it is again noted that Applicant has not clearly, precisely or deliberately set forth the metes and bounds of the claimed subject matter such that the skilled artisan would have been reasonably apprised of the scope of the subject matter for which Applicant is seeking protection. For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Due to the ambiguity of the claim language, the claimed invention(s) will be interpreted to read upon embodiments wherein the claimed composition of active agents is *not* closed to the inclusion of additional amino acid elements for the purposes of examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287; 1972), already of record, for the reasons of record set forth at pages 8-10 of the previous Office Action October 4, 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the instant composition of the current invention consists only of arginine, leucine, isoleucine and valine and that the reference to Winitz discloses compositions with many additional amino acids, which are clearly prohibited by the claims as amended.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

In light of the manner in which the present claims are written, the fact that Applicant intends the specific "amino acid component" to be limited solely to the use of arginine, leucine, isoleucine and valine does not actually preclude the presence of additional amino acids in the composition because the overall composition as a whole is open to the inclusion of additional components resulting from the use of the transitional language of "comprises" and "further comprises" (see present claim 1, for example). Though such additional amino acids may not be present in the "amino acid component" *per se*, the claim(s) as presently written do not prohibit the inclusion of additional amino acids as a part of the claimed composition as a whole. As stated *supra* (please see above, under "Claim Rejections-35 U.S.C. 112, Second Paragraph"), the composition as a whole is a homogenous mixture and clearly allows for other components due to the fact that Applicant describes the *overall* composition with open language. The fact that a single portion of the composition may be limited to four amino acids does not limit the generic structure of the composition as a whole, particularly in view of the fact that the conflicting transitional language of "comprises" and "consists of" fails to clearly, precisely and deliberately set forth the embodiment that Applicant intends to presently claim. Accordingly, Winitz properly anticipates the present claims, even though it teaches the use of additional amino acids aside from L-arginine, L-leucine,

L-isoleucine and L-valine, because the instant claims do not explicitly prohibit the inclusion of additional elements, such as, e.g., additional amino acids, due to the ambiguity in the transitional language.

For these reasons, and those previously made of record at pages 8-10 of the previous Office Action dated October 4, 2006, rejection of claims 1 and 6-7 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287; 1972) in view of Durst (U.S. Patent No. 3,434,843; 1969) and Millman (U.S. Patent No. 4,871,550; 1989), each already of record, for the reasons of record set forth at pages 10-13 of the previous Office Action dated October 4, 2006, of which said reasons are herein incorporated by reference.

Regarding the newly amended limitation directed to dosage amounts "per dosage" as recited in present claim 3, the determination of the optimum amounts of the active ingredients per dosage of the overall composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the

currently claimed specific dosage amounts are not seen to be inconsistent with that which would have been determined by the skilled artisan. Additionally, in the absence of any evidence demonstrating the criticality of such concentrations, the optimization of the dosage amounts to maximize the efficacy of a composition when administered to an individual is considered a routine skill of the artisan. Please reference MPEP §2144.05.

In addition, the concentration of the active ingredient(s) is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Applicant relies on the remarks presented against the application of Winitz under 35 U.S.C. 102(b) and further submits that the secondary references to Durst and Millman do not cure the deficiencies of Winitz because none of the cited references mention or suggest the use of only the four specifically claimed amino acids (i.e., arginine, leucine, isoleucine, valine).

Applicant's remarks have been fully and carefully considered in their entirety, but fail to be persuasive.

In light of the manner in which the present claims are written, the fact that Applicant intends the specific "amino acid component" to be limited solely to the use of arginine, leucine, isoleucine and valine does not actually preclude the presence of additional amino acids in the composition because the overall composition as a whole is open to the inclusion of additional components resulting from the use of the transitional language of "comprises" and "further comprises" (see present claim 1, for example). Though such additional amino acids may not be present in the "amino acid component" *per se*, the claim(s) as presently written do not prohibit the inclusion of additional amino acids as a part of the claimed composition as a whole. As stated *supra* (please see above, under "Claim Rejections-35 U.S.C. 112,

Second Paragraph"), the composition as a whole is a homogenous mixture and clearly allows for other components due to the fact that Applicant describes the *overall* composition with open language. The fact that a single portion of the composition may be limited to four amino acids does not limit the generic structure of the composition as a whole, particularly in view of the fact that the conflicting transitional language of "comprises" and "consists of" fails to clearly, precisely and deliberately set forth the embodiment that Applicant intends to presently claim. Accordingly, Winitz properly applies as prior art over the present claims, even though it teaches the use of additional amino acids aside from L-arginine, L-leucine, L-isoleucine and L-valine, because the instant claims do not explicitly prohibit the inclusion of additional elements, such as, e.g., additional amino acids, due to the ambiguity in the transitional language.

Further, regarding Applicant's assertions that the cited references to Durst and Millman teach compositions with many additional amino acids, where the presently amended claims are limited to only four amino acids (i.e., arginine, leucine, isoleucine and valine), Applicant is directed to the Examiner's comments provided *supra* with regard to Winitz regarding the presence of additional amino acids in the claimed composition, of which said comments apply equally to the teachings of Durst and Millman.

For these reasons, and those previously made of record at pages 10-13 of the previous Office Action dated October 4, 2006, rejection of claims 1-3 remains proper and is **maintained**.

Claims 6-9 and 12-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990), Dudrick et al. (U.S. Patent No. 5,026,721; 1991) and Boynton et al. (U.S. Patent No. 5,07,624; Issued 1992, Priority to 1987), each already of record, for the reasons of record set forth at pages 13-16 of the previous Office Action dated October 4, 2006, of which said reasons are herein incorporated by reference.

Regarding the newly amended limitation directed to dosage amounts "per dosage" as recited in present claim 9, the determination of the optimum amounts of the active ingredients per dosage of the overall composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with that which would have been determined by the skilled artisan. Additionally, in the absence of any evidence demonstrating the criticality of such concentrations, the optimization of the dosage amounts to maximize the efficacy of a composition when administered to an individual is considered a routine skill of the artisan. Please reference MPEP §2144.05.

In addition, the concentration of the active ingredient(s) is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Applicant traverses the instant rejection, stating that the presently claimed composition with only four amino acids is highly effective in promoting muscle growth and excludes lysine from the composition. Applicant additionally states that, at the time of the invention, arginine and lysine were typically combined because lysine inhibited the growth of herpes 1 and 2 virus, which arginine "tends to promote" (see page 7 of Applicant's remarks) and alleges that a skilled artisan at the time of the current

invention would have had no motivation to create a composition with arginine that did not also include lysine. Applicant argues that the Dudrick et al. reference teaches the use of concomitant lysine, which is excluded from the present claims, and further submits that there is no disclosure in Rudman et al. suggesting the combined use of leucine, isoleucine and valine together.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

Regarding the exclusion of lysine from the presently claimed composition, the fact that Applicant intends the specific "amino acid component" to be limited solely to the use of arginine, leucine, isoleucine and valine does not actually preclude the presence of additional amino acids in the composition because the overall composition as a whole is open to the inclusion of additional components resulting from the use of the transitional language of "comprises" and "further comprises" (see present claims 6 or 11, for example). Though such additional amino acids may not be present in the "amino acid component" *per se*, the claim as presently written does not prohibit the inclusion of additional amino acids as a part of the claimed composition as a whole. As stated *supra*, the ambiguity between the open transitional language of "comprises" and the closed transitional language of "consists of" does not clearly or precisely set forth whether the composition is, in fact, open to the inclusion of additional elements or if it is closed to the inclusion of additional elements. However, in view of the fact that the overall composition is described using open transitional language, and, thus, does not preclude the inclusion of additional unrecited elements (i.e., including additional amino acids), the claimed composition is interpreted to read upon embodiments wherein the overall composition does not exclude the presence of additional amino acids.

Furthermore, Applicant's arguments that the art would teach away from the exclusion of lysine from an arginine-containing composition in light of the herpes virus promoting effects of arginine, Applicant is first reminded that, as discussed *supra*, the claims do not definitively exclude lysine from the composition. However, even if the claims did exclude lysine, it is noted that Applicant's assertion that

one of ordinary skill would have necessarily included lysine in combination with the arginine component is unsubstantiated by any evidence and is, therefore, not persuasive. Please reference MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)." It is also noted that although the presence of arginine alone may not be preferable to the skilled artisan, since, as Applicant has alleged on the record, it "tends to promote" herpes virus 1 and 2, such does not constitute a teaching away from a non-preferred embodiment, which, in the present case, would be the use of arginine alone in the absence of lysine. Applicant is reminded that, in accordance with the MPEP at §2123, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments."

Applicant's further allegation that one of skill in the art would have had no motivation to use arginine in the absence of lysine is clearly not persuasive because Applicant has provided no evidence that the state of the art at the time of the invention was such that the skilled artisan would have only contemplated administration of arginine in combination with lysine. The fact that arginine "tended to promote" herpes virus is (1) not a guarantee that herpes virus would always develop with arginine administration, (2) not a guarantee that the absence of lysine in combination with arginine would necessarily always result in development of herpes virus and/or (3) not a teaching that the beneficial effects of arginine could only be achieved with concomitant administration of lysine to preclude the development of herpes virus. Accordingly, the conspicuous absence of any evidence in the record to support the allegation that the state of the art was such at the time of the invention that the skilled artisan would have only contemplated the administration of arginine with lysine further supports the conclusion that the skilled artisan would have viewed the administration of arginine in combination with lysine as a preferable, but not required, combination of agents.

Regarding the combined usage of leucine, isoleucine and valine, Applicant's assertion that there is no disclosure in Rudman et al. regarding the concomitant administration of leucine, isoleucine and valine is not persuasive. Rudman et al. teaches the administration of arginine for enhancing the release of growth hormone and increasing the muscle to fat ratio, i.e., increasing muscle mass, and Dudrick et al. teaches the administration of L-arginine, L-leucine, L-isoleucine and L-valine compositions for enhancing physical performance, particularly improving muscle growth and strength. Though Rudman et al. does not expressly teach the concomitant administration of leucine, isoleucine and valine, such does not change the fact that Dudrick et al. teaches the concomitant administration of these three amino acids for the same therapeutic purpose of enhancing physical strength and muscle growth for which Rudman et al. teaches the administration of arginine. As a result, the combination of arginine, leucine, isoleucine and valine would have naturally commended itself, and would have been *prima facie* obvious, to one of ordinary skill in the art at the time of the invention because each was known in the art to be used for the same therapeutic objective and, therefore, would have been expected to exert additive, if not synergistic, strength enhancing effects when combined, absent factual evidence to the contrary.

For these reasons, and those previously made of record at pages 13-16 of the previous Office Action dated October 4, 2006, rejection of claims 6-9 and 12-15 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-3, 6-9 and 12-15 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

June 14, 2007

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER